

Amendment and Response Under 37 C.F.R. 1.116

Applicant: David Francischelli et al.

Serial No.: 10/056,806

Filed: January 25, 2002

Docket No.: M190.135.101

Title: SYSTEM AND METHOD OF PERFORMING AN ELECTROSURGICAL PROCEDURE**REMARKS**

The following remarks are in support of this Amendment and Response and are made in response to the Final Office Action mailed May 3, 2004. In that Office Action, the Examiner rejected claims 1-19, 19, 20, and 22-32 under 35 U.S.C. §102(b) as being anticipated by Panescu et al., U.S. Patent No. 5,688,267 ("Panescu"). Claims 1-11, 15, and 22-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu. Claims 16-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu as applied to the claims above, and further in view of the teaching of Mulier et al., U.S. Patent No. 5,897,553 ("Mulier"). Claim 21 was rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu in view of the teachings of Jackson et al., U.S. Patent No. 5,383,874 ("Jackson"), and Edwards, U.S. Patent No. 6,009,877 ("Edwards"). The Examiner's indication that claims 12-14 (although objected for being dependent upon a rejected base claim) would be allowable if rewritten in independent form is noted with appreciation. With this Response, claims 22 and 28 have been amended. Claims 1-32 remain pending in the application and are presented for reconsideration and allowance.

In response to the Examiner's comments in the Final Office Action, Applicant wishes to clarify that arguments presented in the Amendment and Response of March 3, 2004 were not premised upon the order in which a physician might select ablation time and other parameters such as maximum power level, maximum temperature, desired power level, etc. Instead, it was and is contended that the "alternative arrangements" passage relied upon by the Examiner (Panescu, column 12, lines 16-24) is properly interpreted to entail that the physician must initially enter a targeted ablation time *t*. This is also required by the only specific example provided in Panescu (column 11, lines 6-35), and does not, therefore, anticipate or render obvious independent claims 1, 22, and 28. By way of reference, the one specific example (column 11, lines 6-35) describes each of control variables *T*₁, *P*, and *t* as being fixed during ablation. In this context then, the language "in alternative arrangements, the controller 98 can fix any one or more of the control variables *T*₁, *P*, or *t* and vary the remaining one or more of the control variables *T*₁, *P*, or *t* to achieve the desired *D*_{50C} temperature boundary" (column 12, lines 16-19) can only mean that unlike the example in which all control variables are fixed, the

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controller can instead allow one or more of the control variables to vary during ablation. The Examiner has apparently interpreted the word "vary" in the cited passage (column 12, lines 16-24) to mean that the controller, not the physician, initially selects the "varied" control variable. There is no support for this interpretation. Instead, with these "alternative arrangements", the physician first select lesion depth, targeted ablation time, maximum tissue temperature, and maximum power level. From these values, the controller then selects a power level P and an electrode temperature T1. Once ablation has begun, the controller can vary one or more of these variables depending upon feedback from the system; this does not change the fact that the initial "recommended energization time period" is selected by the physician in a manner that is not based upon reference to predetermined length of time information. It is respectfully submitted that based upon this interpretation of Panescu, claims 1, 22, and 28 recite allowable subject matter.

Notwithstanding the above, and in an effort to expedite prosecution of the pending application, claim 22 has been amended to recite an energization look-up table adapted to identify a recommended energization time period for an electrode moving relative to a tissue surface. It is respectfully submitted that this language relates to previously presented claims 15-17, such that no further searching is required. The predetermined time information of amended claim 1 dictates a recommended energization time period while the electrode is moving across tissue. In contrast, even if the power and T1 determination table of Panescu (column 10, lines 28-45) were viewed as teaching or suggesting a methodology for determining ablation time, this table is premised upon a stationary electrode. The Panescu system 10 provides an ablation electrode 16 on a catheter 14 (Panescu, column 4, lines 34-36). Inherent to such a system is that the electrode must remain stationary during ablation; it would be difficult if not impossible to ensure consistent, requisite electrode-tissue contact were the catheter/electrode somehow "moved" while applying an ablative energy. The catheter can be "steered" to initially bring the electrode into contact with the tissue to be ablated; however, once in contact, the catheter remains stationary. In fact, many of the Panescu embodiments include a cap 120 or other structure that penetrates the endocardium, effectively locking the electrode relative to the tissue. Thus, any table attributable to Panescu cannot relate to an electrode moving across tissue.

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The technique by which Panescu describes as corroborating the finite element model from which the table of power and T1 values are determined does not account for a moving electrode. In particular, Panescu, at column 9, line 65 – column 10, line 27, describes (with reference to FIG. 21) an ablation catheter C having an electrode E placed in contact with the tissue surface of a bovine heart H. A second thermistor TM2 is placed inside the cardiac tissue H about 2 millimeters beneath the electrode tip. According to Panescu, the second thermistor TM2 placement corresponds to the hottest tissue temperature region predicted by the finite element simulations. Were Panescu at all concerned with a moving electrode, the second thermistor TM2 would also be required to move with movement of the electrode. Importantly, Panescu does not describe or suggest this approach. In fact, it likely would be impossible to uniformly “move” a thermistor inserted into the thickness of a bovine heart. This failure to account for a moving electrode is not surprising as again, Panescu is concerned only with an ablative procedure in which the ablation electrode is stationary. As such, under any interpretation of the language of column 12, lines 16-24, Panescu does not teach or suggest the limitations of amended claim 22.

Claim 28 has been amended to recite a controller that electronically selects a recommended energization time period by reference to predetermined length of time information that relates to the electrosurgical instrument being moved across a tissue surface. Once again, Panescu does not teach or otherwise suggest at least this limitation.

In light of the above, it is respectfully submitted that claims 1, 22, and 28 are allowable over the cited references. Claims 2-21 and 32 depend from amended claim 1; claims 23-27 depend from amended claim 22; and claims 29-31 depend from amended claim 28. For at least the foregoing reasons, then, claims 2-21, 23-27, and 29-32 are allowable.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-32 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-32 is respectfully requested.

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No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Respectfully submitted,

David Francischelli et al.,

By their attorneys,

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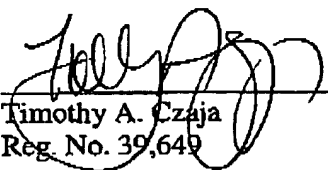
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The undersigned hereby certifies that this paper or papers, as described herein, are being transmitted via telefacsimile to the USPTO, and to the attention of Examiner Peffley of Group Art Unit 3700, at Fax No. (703) 872-9303 on this 6 day of July, 2004.

By 
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